Complete Summary

GUIDELINE TITLE

Premature rupture of membranes.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Premature rupture of membranes. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2007 Apr. 13 p. (ACOG practice bulletin; no. 80). [103 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American College of Obstetricians and Gynecologists (ACOG). Premature rupture of membranes. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 1998 Jun. 10 p. (ACOG practice bulletin; no. 1).

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Premature rupture of membranes (PROM) in pregnancy

GUIDELINE CATEGORY

Diagnosis
Evaluation

Management
Prevention

CLINICAL SPECIALTY

Obstetrics and Gynecology
Pediatrics

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To review the current understanding of premature rupture of membranes (PROM) and to provide management guidelines that have been validated by appropriately conducted outcome-based research

TARGET POPULATION

Pregnant women with suspected premature rupture of membranes

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. History and physical examination including sterile speculum examination and visualization of fluid passing from the cervical canal
2. Ultrasound examination of amniotic fluid volume
3. Ultrasound-guided transabdominal instillation of indigo carmine dye followed by observation for passage of blue fluid from the vagina
4. Assessment of fetal presentation, gestational age, and well-being
5. Fetal heart rate monitoring and uterine activity monitoring to assess fetal status

Management

1. Oxytocin for induction of labor (32 to 36 weeks of gestation)
2. Expectant management (stable condition and less than 30 to 32 weeks of gestation)
3. Ultrasound assessments of amniotic fluid volume and cervical length (not recommended in isolation from other management methods)
4. Tocolysis
5. Prophylactic or therapeutic antibiotics:
    - Intravenous ampicillin and erythromycin followed by oral amoxicillin and erythromycin
    - Oral erythromycin and amoxicillin-clavulanic acid (not recommended)
6. Antenatal corticosteroids
7. Home care

8. Cervical cerclage treatment
9. Treatment for patients with herpes simplex virus infection

MAJOR OUTCOMES CONSIDERED

- Risk factors associated with premature rupture of membranes (PROM)
- Rate of maternal and fetal complications associated with PROM
- Infant survival rates in pregnancies complicated by PROM

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and American College of Obstetricians and Gynecologists' (ACOG's) own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and November 2006. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force.

I Evidence obtained from at least one properly designed randomized controlled trial.

II-1 Evidence obtained from well-designed controlled trials without randomization.

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of "Major Recommendations" field.

The following recommendations and conclusions are based on good and consistent scientific evidence (Level A):

- For women with premature rupture of membranes (PROM) at term, labor should be induced at the time of presentation, generally with oxytocin infusion, to reduce the risk of chorioamnionitis.
- Patients with PROM before 32 weeks of gestation should be cared for expectantly until 33 completed weeks of gestation if no maternal or fetal contraindications exist.
- A 48-hour course of intravenous ampicillin and erythromycin followed by 5 days of amoxicillin and erythromycin is recommended during expectant management of preterm PROM remote from term to prolong pregnancy and to reduce infectious and gestational age-dependent neonatal morbidity.
- All women with PROM and a viable fetus, including those known to be carriers of group B streptococci and those who give birth before carrier status can be delineated, should receive intrapartum chemoprophylaxis to prevent vertical transmission of group B streptococci regardless of earlier treatments.
- A single course of antenatal corticosteroids should be administered to women with PROM before 32 weeks of gestation to reduce the risks of respiratory distress syndrome (RDS), perinatal mortality, and other morbidities.

The following recommendations and conclusions are based on limited and inconsistent scientific evidence (Level B):

- Delivery is recommended when PROM occurs at or beyond 34 weeks of gestation.
- With PROM at 32 to 33 completed weeks of gestation, labor induction may be considered if fetal pulmonary maturity has been documented.
- Digital cervical examinations should be avoided in patients with PROM unless they are in active labor or imminent delivery is anticipated.

The following recommendations and conclusions are based primarily on consensus and expert opinion (Level C):

- A specific recommendation for or against tocolysis administration cannot be made.
- The efficacy of corticosteroid use at 32–33 completed weeks is unclear based on available evidence, but treatment may be beneficial particularly if pulmonary immaturity is documented.
- For a woman with preterm PROM and a viable fetus, the safety of expectant management at home has not been established.

Table: Management of Premature Rupture of Membranes Chronologically

Gestational Age	Management
Term (37 weeks or more)	• Proceed to delivery, usually by induction of labor • Group B streptococcal prophylaxis recommended
Near term (34 weeks to 36 completed)	• Same as for term
Preterm (32 weeks to 33 completed weeks)	• Expectant management, unless fetal pulmonary maturity is documented • Group B streptococcal prophylaxis recommended • Corticosteroid—no consensus, but some experts recommend • Antibiotics recommended to prolong latency if there are no contraindications
Preterm (24 weeks to 31 completed weeks)	• Expectant management • Group B streptococcal prophylaxis recommended • Single-course corticosteroid use recommended • Tocolytics—no consensus • Antibiotics recommended to prolong latency if there are no contraindications
Less than 24 weeks*	• Patient counseling • Expectant management or induction of labor • Group B streptococcal prophylaxis is not recommended • Corticosteroids are not recommended • Antibiotics—there are incomplete data on use in prolonging latency

*The combination of birthweight, gestational age, and sex provide the best estimate of chances of survival and should be considered in individual cases.

Definitions:

Grades of Evidence

I Evidence obtained from at least one properly designed randomized controlled trial.

II-1 Evidence obtained from well-designed controlled trials without randomization.

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments could also be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Levels of Recommendations

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Benefits

Improved understanding and management of premature rupture of membranes (PROM)

POTENTIAL HARMS

Amoxicillin–clavulanic acid should be avoided because of the increased risk of neonatal necrotizing enterocolitis.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1998 Jun (revised 2007 Apr)

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUIDELINE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Obstetrics

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

Proposed performance measures are included in the original guideline document.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on January 14, 2005. This NGC summary was updated by ECRI Institute on October 4, 2007. The updated information was verified by the guideline developer on December 3, 2007.

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